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1       "Blood Regulation Device"

2

3       The present invention relates to stents for  
4       connecting a first compartment to a second  
5       compartment. In particular, the invention relates  
6       to cardiovascular stents e.g. for connection of the  
7       left ventricle of the heart to a coronary artery.

8

9       Coronary artery disease is a major problem throughout  
10      the world, particularly in Western society.  
11      Coronary arteries, as well as other blood vessels,  
12      can become clogged with plaque, impairing the  
13      efficiency of the heart's pumping action. This can  
14      lead to heart attacks, angina and death.

15

16      A number of methods are used to treat clogged  
17      coronary arteries such as bypass operations or  
18      balloon angioplasty.

19

20      In bypass operations one or more venous segments are  
21      inserted between the aorta and the coronary arteries  
22      to bypass the blocked portion of the coronary artery  
23      such that an unobstructed flow of blood and thus

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10 / 526290  
BT01 Rec'd PCT/PTR 01 MAR 2005

1       blood supply to the heart is achieved. More than  
2       500,000 bypass procedures are performed in the US  
3       every year.

4

5       However, bypass surgery is a very intrusive  
6       procedure requiring expensive and time-consuming  
7       surgery. During a bypass operation, an incision is  
8       made through the patient's skin and the patient is  
9       placed on a bypass pump such that the heart can be  
10      operated on, while it is not beating. A saphenous  
11      vein graft is harvested from a patient's leg and the  
12      vein is then grafted into position between the aorta  
13      and the coronary artery to allow unobstructed blood  
14      flow. This surgery is both traumatic to the patient  
15      and requires a substantial period of time in  
16      hospital and prolonged convalescence.

17

18      In some circumstances a balloon angioplasty  
19      procedure is used instead of the above method, to  
20      treat coronary artery plaque occlusion. In this  
21      case a deflated balloon catheter is placed within  
22      the narrowed segment of the coronary artery. The  
23      balloon is then inflated to a high pressure,  
24      transmitting circumferential pressure to the plaque  
25      occluding the artery, compressing the plaque and  
26      thus increasing the diameter through which blood can  
27      flow.

28

29      Although balloon angioplasty is minimally invasive,  
30      this procedure can only be used in a limited number  
31      of circumstances.

32

1     In addition to the two techniques discussed above,  
2     which have been traditionally used to treat coronary  
3     artery occlusion, a more recent procedure allows a  
4     stent to be positioned between the coronary artery  
5     and the left ventricle of the heart such that blood  
6     can flow unobstructed from the left ventricle of the  
7     heart to the coronary artery, bypassing the occluded  
8     portion of the coronary artery. The stent may be  
9     positioned between the left ventricle of the heart  
10    and the coronary artery using a less invasive  
11    procedure than that required for coronary bypass  
12    surgery.

13

14    Typically the stent is a conduit with a passage  
15    extending longitudinally therethrough. Generally a  
16    stent is cylindrical in cross section and is  
17    generally an elongate tube.

18

19    A disadvantage of providing a stent extending from  
20    the left ventricle of the heart to the coronary  
21    artery is that during diastole blood may reflux from  
22    the coronary artery back into the left ventricle of  
23    the heart. Such refluxes of blood are undesirable.

24

25    Some reports have indicated that backflow of  
26    oxygenated blood back into the left ventricle  
27    chamber of the heart during diastole can cause the  
28    myocardium to receive an inadequate supply of  
29    blood. This can lead to the myocardium becoming  
30    ischemic. Indeed, some studies have suggested that  
31    measurement of the blood flow during systole and the  
32    backflow during diastole indicates that only a 30

1 percent net flow rate of blood from the left  
2 ventricle chamber into the artery is achieved  
3 following introduction of a stent between the two  
4 compartments.

5  
6 There remains a need for improved (more efficient)  
7 stents.

8  
9 The present inventor has overcome a number of  
10 problems of stents of the prior art.

11  
12 According to a first aspect of the present invention  
13 there is provided a cardiovascular stent comprising  
14 a generally tubular body and a synthetic one-way  
15 valve capable of moving from a first open position  
16 to a second closed position, wherein, in use,  
17 movement of fluid, e.g. blood, in a first direction  
18 through the stent causes the valve to adopt the open  
19 position and movement of fluid in a second opposite  
20 direction causes the valve to adopt the closed  
21 position.

22  
23 The valve is deemed to be in the closed position  
24 when it restricts the passage of fluid in the second  
25 direction e.g. from a second compartment to a first  
26 compartment. A stent as described by the present  
27 invention can be used to enable the movement of  
28 fluid from a proximal position in a first  
29 cardiovascular compartment to a distal position in  
30 the same cardiovascular compartment or a different  
31 cardiovascular compartment.

32

1 Preferably in the closed position, the valve allows  
2 movement of fluid in the second direction of less  
3 than 40% that when the valve is in the open  
4 position.

5

6 More preferably in the closed position the valve  
7 allows movement of fluid in a second direction of  
8 less than 30%, preferably less than 20%, even more  
9 preferably less than 10%, even more preferably less  
10 than 5%, even more preferably less than 2% and most  
11 preferably less than 1% that when the valve is in  
12 the open position.

13

14 A stent with a synthetic valve is advantageous as it  
15 can restrict the passage of fluid in a second  
16 direction, e.g. from a second compartment to a first  
17 compartment, e.g. from a coronary artery to the left  
18 ventricle of the heart. This provides for an  
19 increase in the net flow rate of blood from the  
20 first compartment into the second compartment and  
21 minimises the likelihood of e.g. the myocardium, of  
22 which the coronary artery provides the blood supply,  
23 receiving an inadequate supply of blood.

24

25 In such an embodiment the movement of fluid in the  
26 first direction e.g. from the first compartment to  
27 the second compartment causes a pressure difference  
28 across the valve sufficient to cause the valve to  
29 adopt the open position. Fluid flow in the second  
30 opposite direction, e.g. from the second compartment  
31 to the first compartment across the valve, causes  
32 the valve to adopt the closed position.

1

2     Further, the use of a synthetic valve has the  
3     further advantage that a vein does not need to be  
4     harvested from the patient.

5

6     Preferably in the absence of movement of fluid in  
7     either a first or second direction the valve adopts  
8     the closed position. Thus preferably the valve is  
9     resiliently biased towards the closed configuration.

10

11    Preferably the stent is for use in linking  
12    cardiovascular compartments.

13

14    Preferably the first compartment is a first  
15    cardiovascular compartment and the second  
16    compartment is a second cardiovascular compartment.

17

18    A cardiovascular stent is a stent suitable for use  
19    to link one part of a cardiovascular compartment to  
20    another part of the same cardiovascular compartment  
21    or to another cardiovascular compartment.

22

23    A cardiovascular compartment is defined as any organ  
24    or any structure of the circulatory system including  
25    an artery, vein or chamber of the heart.

26

27    In a preferred embodiment the stent is for use as a  
28    stent between the left ventricle of the heart and a  
29    coronary artery.

30

31    Preferably the valve is formed from resilient  
32    material.

1  
2     A valve formed from resilient material is  
3     advantageous as it requires few mechanical  
4     components to enable the valve to move between the  
5     open and closed positions and thus there is less  
6     likelihood of damage to red blood corpuscles moved  
7     through the stent.

8

9     Preferably the flexible resilient material is a  
10    suitable biostable biocompatible polymer.

11

12    Preferably the flexible resilient material includes  
13    Elast-Eon™, Biomer or Biospan.

14

15    Details of the polymer Elast-Eon™ can be found in  
16    WO98/13405, WO92/00338, WO92/09467, WO99/01496.

17

18    In an embodiment in which the valve is formed from  
19    resilient material, in the closed position,  
20    preferably at least a portion of the aperture formed  
21    by the resilient material of the valve is  
22    ellipsoidal shape in cross-section. This  
23    ellipsoidal shape restricts blood flow from the  
24    second cardiovascular compartment into the first  
25    cardiovascular compartment.

26

27    Preferably the valve is constructed such that  
28    movement of fluid such as blood in the first  
29    direction through the stent urges the resilient  
30    material of the valve to adopt a configuration in  
31    which the aperture defined by the material is  
32    substantially circular in cross-section thereby

1 enabling increased fluid to flow through the valve  
2 and thus through the stent. Hence, with the  
3 circular aperture increased flow from the first  
4 cardiovascular compartment into the second  
5 cardiovascular compartment is provided.

6

7 In an alternative embodiment the valve may comprise  
8 at least two leaflets formed from resilient material  
9 which when fluid is flowing in the second direction  
10 through the stent or when no fluid is flowing  
11 through the stent, the leaflets are urged towards  
12 each other such that the passage of fluid e.g. blood  
13 is minimised. In this embodiment, movement of fluid  
14 in the first direction e.g. from a first compartment  
15 to a second compartment urges the leaflets of the  
16 valve to move apart from each other enabling the  
17 passage of fluid through the stent.

18

19 The valve may be located at any position in the  
20 stent.

21

22 Preferably the valve is located at either end of the  
23 stent.

24

25 Such an embodiment is advantageous as a valve  
26 portion of the stent can extend into a  
27 cardiovascular compartment. This can be of  
28 importance, for example, if the stent is for use  
29 between the left ventricle of the heart and the  
30 coronary artery as positioning of the valve in the  
31 heart muscle may restrict the movement of the valve,  
32 as the muscle contracts and relaxes.

1

2 Preferably the valve is integral to the stent.

3

4 Although a stent may be located and then valve means  
5 provided on the stent, it is preferable if the stent  
6 and valve are provided in one unit such that they  
7 can be located between the cardiovascular  
8 compartments in a single procedure.

9

10 The stent may be constructed of any suitable  
11 material.

12

13 The stent may comprise a suitable rigid  
14 biocompatible metal which may include, but is not  
15 limited to one or more of stainless steel, spring  
16 steel, Nitinol and / or a flexible resilient  
17 material.

18

19 Preferably the stent may be constructed from  
20 scaffold mesh.

21

22 Preferably the stent comprises a flange portion  
23 located towards or at one end of the stent.

24

25 This is advantageous as when the stent is pushed  
26 into tissue to provide a passage between two  
27 compartments the depth of the stent in the tissue  
28 can be controlled by the flange portion. If, for  
29 example, the flange portion is towards or at the  
30 rear portion of the stent, the front portion being  
31 the portion inserted first into the tissue, on  
32 pushing the stent into tissue from one compartment

1 to another the flange provided at the rear will  
2 prevent the stent being pushed too far into the  
3 tissue, ensuring that the lumen of the stent extends  
4 from a first compartment into a second compartment.  
5 Moreover the flange portion can also be used to  
6 secure the stent in position, the tissue at around  
7 the flange preventing movement of the stent from a  
8 first compartment to a second compartment.

9

10 In a preferred embodiment, the valve comprises at  
11 least one cantilever member, having a first end and  
12 a second end, said cantilever member being pivoted  
13 at said first end to the stent, the cantilever  
14 member being resiliently pivotable from a first  
15 extended position in which the valve is in a closed  
16 position to a second position in which the valve is  
17 open. In a preferred example of such an embodiment  
18 when the second end of the cantilever member is in  
19 the extended position the material forming the valve  
20 and defining the aperture of the valve, when in the  
21 open position, is pulled such that the area of the  
22 aperture formed by the material is decreased.

23

24 In such a preferred example of this embodiment,  
25 movement of fluid in a first direction through the  
26 stent causes the second end of the cantilever member  
27 to resiliently move radially inwards towards the  
28 central longitudinal axis of the stent. This  
29 movement of the second end of the cantilever member  
30 causes the material forming the valve and defining  
31 the aperture of the valve to form a larger aperture  
32 (preferably substantially circular) in cross section

1       enabling increased fluid to flow through the valve.  
2       As the fluid flow in the first direction is reduced  
3       or when there is no fluid flow in the first  
4       direction, the cantilever member resiliently pivots  
5       to the extended position. This movement of the  
6       second end of the cantilever member to the extended  
7       position causes the material forming the valve and  
8       defining the aperture of the valve to be pulled to  
9       form an aperture of reduced area in cross section.  
10      As the aperture has less area in cross section than  
11      the substantially circular aperture, fluid flow in  
12      both the first and second directions is restricted.  
13

14     More preferably, the valve comprises two cantilever  
15     members. In this embodiment the two cantilever  
16     members are resiliently pivoted at first ends of the  
17     members to the stent. When no fluid is flowing  
18     through the stent the second ends of the cantilever  
19     members pivot radially outwards to an extended  
20     position. Preferably radially greater than the  
21     circumference of the stent. When the second ends of  
22     the cantilever members are in the extended positions  
23     the material forming the valve and defining the  
24     aperture of the valve when in the open position is  
25     held such that the area of the aperture formed by  
26     the material is decreased and forms an ellipsoid in  
27     cross section.

28  
29     Such an embodiment may function as follows: Movement  
30     of fluid in a first direction through the stent  
31     causes the second ends of the cantilever members to  
32     resiliently move radially inwards towards the

1 central longitudinal axis of the stent. This  
2 movement of the second ends of the cantilever  
3 members causes the material forming the valve and  
4 defining the aperture of the valve to form a  
5 substantially circular aperture in cross section  
6 enabling blood to flow through the valve.

7

8 As the fluid flow in the first direction is reduced,  
9 or when there is no fluid flow in the first  
10 direction, the second ends of the cantilever members  
11 again resiliently pivot to an extended position.  
12 The movement of the second ends of the cantilever  
13 members to their extended positions again causes the  
14 material forming the valve and defining the aperture  
15 of the valve to be pulled to form an ellipsoid  
16 aperture of reduced area in cross section. As the  
17 aperture has less area in cross section than the  
18 substantially circular aperture, fluid flow in both  
19 the first and second directions is restricted.

20

21 With the circular cross section increased flow  
22 through the stent is enabled and with the  
23 ellipsoidal cross section flow in the second  
24 direction is minimised.

25

26 In such an embodiment, the aperture formed by the  
27 resilient material is preferably pulled from a  
28 substantially circular cross section to a  
29 substantially ellipsoidal cross section, which, in  
30 use, restricts the flow of fluid from a second  
31 compartment toward a first compartment.

32

1     Preferably the stent is constructed such that it can  
2     be expanded in diameter from a "collapsed"  
3     configuration to an "expanded" configuration,  
4     wherein, in the collapsed configuration, the stent  
5     is of narrower diameter than in the expanded  
6     configuration.

7

8     Such a structure enables the stent to be suitably  
9     placed in the body in the narrowed collapsed  
10    configuration and then expanded from its collapsed  
11    configuration to a fully expanded configuration.

12

13    The diameter of the stent can be increased from the  
14    collapsed to expanded position using any suitable  
15    procedures, for example, using a balloon angioplasty  
16    procedure.

17

18    In order to position such a stent, the stent, in a  
19    collapsed position, may be delivered to the desired  
20    location in the body, for example, the heart muscle  
21    between the left ventricle and a coronary artery on  
22    a catheter. The suitably located stents may then be  
23    deployed by expanding a balloon placed in the stent  
24    such that the diameter of the stent increases from  
25    that of the collapsed stent position to the  
26    increased diameter of the stent in the expanded  
27    position.

28

29    Further to expanding the diameter of the stent by  
30    the balloon the stent locks in the expanded  
31    position, holding the stent against the heart muscle

1 and maintaining the stent in its expanded position  
2 with increased diameter.

3

4 The collapsed stent can be placed by suitable  
5 minimally invasive techniques such as percutaneous  
6 delivery.

7

8 In an alternative embodiment the stent may be  
9 constructed of material with memory such that once  
10 suitably placed in the body the diameter of the  
11 stent expands from a collapsed position to a fully  
12 expanded position.

13

14 For example, in such an embodiment, the stent may  
15 adopt a collapsed position at low temperatures, for  
16 example temperatures below body temperature, but an  
17 expanded position at body temperature.

18

19 In one preferred embodiment, the valve of the stent  
20 is moved to a closed position on increasing the  
21 diameter of the stent from a collapsed position to  
22 an expanded position when the stent is suitably  
23 positioned in the body.

24

25 In particularly preferred embodiments the valve  
26 comprises at least one cantilever member as  
27 discussed above. Expansion of diameter of the stent  
28 e.g. on deployment of the stent, causes the valve to  
29 adopt the closed configuration.

30

31 In this embodiment, the cantilever member may be  
32 resiliently pivoted at a first end to the stent such

1       that on expansion of the diameter of the stent a  
2       second end of the cantilever member pivots to an  
3       extended position in which the material forming the  
4       valve and defining the aperture of the valve when in  
5       the open position is pulled such that the area of  
6       the aperture formed by the material is decreased.

7

8       More preferably the valve comprises two cantilever  
9       members which, on deployment of the stent, cause the  
10      diameter of the stent to expand from a collapsed  
11      configuration in which the valve portion of the  
12      stent is in an open position to an expanded  
13      configuration in which the valve is in a closed  
14      position. With the circular cross section increased  
15      flow through the stent is enabled and with the  
16      ellipsoidal cross section flow in the second  
17      direction is minimised.

18

19      In such an embodiment, the aperture formed by the  
20      resilient material is preferably pulled from a  
21      substantially circular cross section to a  
22      substantially ellipsoidal cross section, which, in  
23      use, restricts the flow of fluid from a second  
24      compartment toward a first compartment.

25

26      The diameter and length of the stent depends on its  
27      use. For example, the stent may be of suitable  
28      length to extend between the left ventricle of heart  
29      and coronary artery.

30

31      Preferably the stent is two to fifteen millimetres  
32      in diameter.

1  
2     The stent may be constructed such that a number of  
3     stents may be positioned "end to end" to increase  
4     the effective length of the stent arrangement.

5

6     Thus, in one preferred embodiment the stent is  
7     resiliently deformable at at least one end to  
8     receive and enable connection with a second stent.

9

10    In an alternative embodiment the stent may be shaped  
11    at one or both ends to enable connection to a second  
12    stent.

13

14    The stent may comprise drug coatings or chemical and  
15    / or mechanical coatings such as a TEFLON™ membrane  
16    to minimise stenosis.

17

18    As described above, stents of the present invention  
19    may be used to link or repair two cardiovascular  
20    compartments.

21

22    For example, stents of the invention may be used to  
23    link a coronary artery to the left ventricle of the  
24    heart.

25

26    Stents of the present invention may also be used in  
27    non coronary structures e.g. non coronary veins and  
28    / or arteries.

29

30    For example, the stents may be used to link a first  
31    portion of an ascending venous structure such as the  
32    saphenous vein and a second portion of the same

1        ascending venous structure. If the region between  
2        the first and second portions of the femoral artery  
3        is damaged or occluded, a stent of the invention may  
4        be located between the first and second portions to  
5        enable the movement of blood from the first portion  
6        to the second portion.

7

8        Thus in use, a stent of the present invention may be  
9        provided between a first and second portion of a  
10      vein e.g. a saphenous vein, to allow blood to flow  
11      from the first portion to the second portion, but  
12      restrict blood flow from the second portion to the  
13      first portion. Such an arrangement could be used to  
14      treat varicose veins.

15

16      In a second aspect of the present invention there is  
17      provided a method for treating a full or partial  
18      occlusion of a blood vessel comprising the step of  
19

20            providing stent means wherein said stent means  
21            comprise at least one stent of the first aspect  
22            of the invention,

23

24            a first end of the lumen of the stent means  
25            being in communication with a cardiovascular  
26            compartment on one side of the occlusion,

27

28            the second end of the lumen of the stent means  
29            being in communication with a cardiovascular  
30            compartment on the other side of the occlusion  
31            allowing blood flow from the first side to the

1           second side of the cardiovascular compartment  
2           through the lumen of the stent means.

3

4       The cardiovascular compartments on each side of the  
5       occlusion may be in same the blood vessel in which  
6       the occlusion is present.

7

8       In alternative embodiments the cardiovascular  
9       compartments may be different compartments, for  
10      example the left ventricle of the heart and a  
11      coronary artery.

12

13      The stent means may comprise a single stent.  
14      Alternatively the stent means may comprise a  
15      plurality of stents longitudinally aligned to allow  
16      the flow of blood from a stent at a first end of the  
17      stent means to a stent at a second end of the stent  
18      means.

19

20      Preferably the stent means comprise a single stent  
21      of the first aspect of the invention.

22

23      In preferred embodiments the method further  
24      comprises the step of positioning the stent means  
25      between the compartments, increasing the diameter of  
26      the stent means from a reduced diameter in a  
27      collapsed position to an increased diameter in an  
28      expanded position.

29

30      In particularly preferred embodiments the method  
31      comprises the steps of

32

1       inserting the stent into position between a  
2       first cardiovascular compartment and a second  
3       cardiovascular compartment;

4

5       expanding the diameter of the stent such that  
6       the valve is moved to the closed position, but  
7       can move to the open position when fluid flows  
8       in a first direction from a first  
9       cardiovascular compartment to a second  
10      cardiovascular compartment.

11

12      According to a further aspect of the invention there  
13      is provided a method for treating varicose veins  
14      comprising positioning stent means comprising at  
15      least one stent of the first aspect of the invention  
16      in a vein or replacing all or part of a vein with  
17      stent means comprising at least one stent of the  
18      first aspect of the invention.

19

20      As above, stent means may comprise a plurality of  
21      stents longitudinally aligned to allow the flow of  
22      fluid from a stent at a first end of the stent means  
23      to a stent at a second end of the stent means.

24

25      As described above, in a preferred embodiment of a  
26      first aspect of the invention a stent comprising a  
27      valve comprising at least one cantilever member is  
28      provided. The use of such a valve is not limited to  
29      uses within the body. Accordingly, in a further  
30      independent aspect there is provided tube means,  
31      said tube means comprising a valve which comprises  
32      at least one cantilever member, having a first end

1 and a second end, said cantilever member being  
2 pivoted at said first end to the tube, the  
3 cantilever member being resiliently pivotable from a  
4 first extended position in which the valve is in a  
5 closed position to a second position in which the  
6 valve is open.

7

8 Tubes comprising such valves may be used to link a  
9 first cardiovascular compartment with a compartment  
10 in a cardiovascular device or vice versa.

11

12 In a further embodiment tubes comprising such valves  
13 may be used to link first and second compartments in  
14 a device to transport fluid, for example blood.

15

16 For example, such tubes comprising at least one  
17 cantilever member can be used in machines or devices  
18 used to move fluid, for example blood, such as  
19 dialysis machines.

20

21 A further independent aspect of the present  
22 invention is a device for the movement of fluid.

23

24 Preferably the fluid is blood.

25

26 The present invention will now be described, by way  
27 of example only, with reference to the accompanying  
28 figures in which;

29

30 Figure 1 is an illustration of an embodiment of  
31 a stent of the present invention extending from

1           the left ventricle of the heart into the  
2           coronary artery;

3

4           Figure 2 is an enlarged view of an embodiment  
5           of a stent of the present invention connecting  
6           the left ventricle of the heart to the coronary  
7           artery;

8

9           Figure 3 is an illustration of an embodiment of  
10          a stent of the present invention wherein a  
11          second end of the stent is in a closed  
12          position;

13

14          Figure 4 (A) is an illustration of an  
15          embodiment of a stent in a collapsed form, (B)  
16          is an illustration of an embodiment of a stent  
17          of the present invention in an expanded form;

18

19          Figure 5 is an illustration of an embodiment of  
20          a stent of the present invention where a second  
21          end of a stent is in an open position;

22

23          Figure 6 is an illustration of at least two  
24          embodiments of stents of the present invention  
25          aligned along their longitudinal axes such that  
26          blood can flow from the lumen of a first stent  
27          to the lumen of a second adjacent stent; and

28

29          Figure 7 is an illustration of stents according  
30          to an embodiment of the present invention  
31          aligned along their longitudinal length wherein  
32          the first stent has a shaped end to receive the

1           second stent and another stent is deformable to  
2           receive a stent inside one end.

3

4       As shown in figure 1, the coronary artery 10 is  
5       known to branch off the aorta 12 and be positioned  
6       along the external surface of the heart wall 14.

7

8       Following oxygenation of the blood, the oxygenated  
9       blood flows from the heart 16 into the aorta 12 and  
10      onto the rest of the body. Some of the oxygenated  
11      blood is circulated along the coronary artery 10 in  
12      order to oxygenate the muscles of the heart. In  
13      some individuals an occlusion is formed within the  
14      coronary artery due to plaque build up. These  
15      occlusions can lead to a variety of symptoms and  
16      diseases ranging from mild angina to heart attack.

17

18      In order to allow blood flow around the occlusion  
19      within the coronary artery and to at least partially  
20      restore the flow of oxygenated blood through the  
21      coronary artery, it is possible to bypass the  
22      blocked portion of the coronary artery by providing  
23      a stent 18 which extends from the left ventricle 20  
24      of the heart into the coronary artery 10, as shown  
25      in figure 2. Location of the stent 18 as shown in  
26      figure 2 allows blood to flow unobstructed from the  
27      left ventricle 20 of the heart to the coronary  
28      artery 10.

29

30      Allowing blood flow past or around occlusions of the  
31      coronary artery 10 using a stent 18 is preferable to  
32      traditional bypass surgery in that the stent 18 may

1       be located and fitted using minimally invasive  
2       techniques. Generally the stents previously used to  
3       connect the left ventricle 20 of the heart to the  
4       coronary artery 10 are stents formed by hollow tubes  
5       comprising biocompatible material such as titanium  
6       alloys, nickel alloys or biocompatible polymers.  
7       These tubes may be provided and located between the  
8       left ventricle 20 of the heart and the coronary  
9       artery 10 in a collapsed position and when suitably  
10      located, expanded from a collapsed position to a  
11      fully expanded position, using an inflatable balloon  
12      catheter or other method.

13

14      Although such stents allow the flow of blood from  
15      the left ventricle 20 of the heart into the coronary  
16      artery, no artificial or mechanical means are  
17      present on conventional stents to restrict the  
18      backflow of blood.

19

20      As shown in figure 3, a stent of the present  
21      invention is provided with a synthetic valve 22, one  
22      example of the valve being a portion of flexible  
23      resilient material located at the second end 24 of  
24      the stent. This flexible resilient material is  
25      preferably integral with the rest of the stent.

26

27      The valve may be formed during manufacture of the  
28      stent, prior to insertion of the stent into the  
29      body.

30

31      Alternatively, as shown in the embodiment of the  
32      stent in figure 4, the valve can be created by the

1 pivotal movement of cantilever members during the  
2 movement of the stent from a collapsed position to  
3 an expanded position, while the stent is located in  
4 the body.

5

6 As shown in figure 4a, in this embodiment, in a  
7 collapsed position, the resilient material, held by  
8 two cantilever members 21, forms a substantially  
9 cylindrical aperture 28.

10

11 The cantilever members are conjoined to the stent at  
12 a first end only and from the rigid biocompatible  
13 metal portion 23 of the stent. On deployment  
14 (expansion of diameter) of the stent, the second  
15 ends of the cantilevers move away from each other to  
16 an extended position. This movement pulls the  
17 resilient material such that its cross sectional  
18 shape is changed from substantially circular to  
19 substantially ellipsoidal. The change in the cross  
20 sectional shape restricts the flow of blood in a  
21 second direction from the second compartment into  
22 the first compartment through the stent. Blood flow  
23 through the stent from a first compartment to a  
24 second compartment causes the material of the  
25 leaflets to be pushed such that the cantilever  
26 members resiliently move towards each other and the  
27 aperture of the valve becomes substantially circular  
28 in cross section. The area of the circular cross  
29 section is larger than the ellipsoidal cross section  
30 and blood can thus easily flow from the first  
31 compartment to the second compartment. During  
32 diastole, when blood is not being pushed from the

1       first compartment to the second compartment, the  
2       pressure of the blood on the material of the valve  
3       decreases. The second ends of the resilient  
4       cantilever members can again move away from each  
5       other and cause the valve material to form an  
6       ellipsoidal cross section.

7

8       It can be appreciated that if more than two  
9       cantilevers are used for example, three, four or  
10      five cantilevers, then on deployment, the cross  
11      sectional shape will not be elliptical, but  
12      substantially triangular, rectangular or pentacle  
13      shaped. Different shaped openings may be used as  
14      appropriate to restrict the flow of blood from the  
15      second compartment to the first compartment. In  
16      addition, different shaped openings can be chosen to  
17      minimise pressure on the arterial wall caused by the  
18      cantilever members.

19

20      In one embodiment, a valve formed from resilient  
21      material does not require expansion of the diameter  
22      of the stent to cause the resilient material to  
23      adopt the closed position. In this embodiment  
24      cantilever members are not required to pull the  
25      material of the valve to a closed position and the  
26      valve is manufactured in the closed position. Blood  
27      flow in a first direction from the first compartment  
28      towards the second compartment causes the resilient  
29      material to adopt an open position.

30

31      In addition to the cantilever members disclosed  
32      herein, different methods of urging the resilient

1 material to a closed position following expansion of  
2 a stent structure from a collapsed position can be  
3 envisaged.

4

5 During systole (contraction of the heart) the blood  
6 is pumped by the heart through the stent 18 from the  
7 first end 26 located at the left ventricle 20 of the  
8 heart towards the second end 24 of the stent located  
9 at the coronary artery. On contraction of the  
10 heart, the blood of the left ventricle of the heart  
11 is moved in a first direction through the stent  
12 causing the valve to move from an ellipsoidal shape  
13 (closed position) to an open (circular cross  
14 sectional shape) position.

15

16 In the closed position the ellipsoidal shape causes  
17 the area through which blood can flow from the  
18 second compartment to the first compartment to be  
19 reduced to 10% the area of the open position of the  
20 valve. The backflow of blood is thus reduced when  
21 blood is not being pumped through the stent from the  
22 first compartment to the second compartment.

23

24 Typically reflux of blood through the valve from the  
25 second compartment to the first compartment may be  
26 25% that which would be expected if the valve is in  
27 the open position.

28

29 The movement of the resilient material in this  
30 manner, from an ellipsoidal shape (closed position)  
31 towards a circular shape (open position), increases  
32 the area of the aperture 28 through which the blood

1 can flow from the first compartment (in this case  
2 the left ventricle of the heart) into the second  
3 compartment (in this case the coronary artery) and  
4 allows the unobstructed flow of blood through the  
5 valve.

6

7 As the pressure of the blood flow through the valve  
8 in a first direction decreases, the resilient  
9 material is urged by the material (and in particular  
10 embodiments the cantilever members of the rigid  
11 portion of the stent) to cause the valve to adopt a  
12 resting position, wherein the aperture of the valve  
13 into the coronary artery forms an ellipsoidal shape.  
14 This change in shape of the aperture reduces the  
15 area of the aperture located at the second  
16 compartment and minimises the blood flow from the  
17 coronary artery into the left ventricle of the  
18 heart.

19

20 Movement of the stent from a collapsed position to  
21 an expanded position causes the stent to be gripped  
22 by the heart muscle. A flange or other projection  
23 may also be provided on the stent to aid location of  
24 the stent.

25

26 As shown in figures 6 and 7 at least two stents can  
27 be aligned along their longitudinal axes such that  
28 blood can be communicated from the lumen of a first  
29 stent to the lumen of a second adjacent stent. By  
30 aligning several stents together, blood may be moved  
31 from a first proximal position to a second distal  
32 position, either between two different

1 cardiovascular compartments such as the left  
2 ventricle of the heart and a coronary artery or  
3 within the same cardiovascular compartments such as  
4 a blood vessel.

5

6 By aligning a number of stents along their  
7 longitudinal axis it is possible to allow blood flow  
8 to be effected over a relatively large distance. In  
9 addition, as each of the stents comprise a valve,  
10 the stents more closely mimic the situation in  
11 actual veins preventing the backflow of blood and  
12 allowing blood to be moved upwards. An example of  
13 when the blood may be required to be moved upwards  
14 is in the leg of a patient when said patient is  
15 standing.

16

17 The valves present on each of the stents allow blood  
18 to be pushed through the valve on contraction of the  
19 heart, but minimise the backward movement of the  
20 blood during diastole. This allows blood to be  
21 moved up the leg and through the body.

22

23 To allow the stents to be conjoined to each other, a  
24 first end of a stent may be capable of deformation  
25 (as shown in figure 7 (30)) to allow a second stent  
26 to be partially inserted therein. Alternatively or  
27 additionally the stent may also be widened (figure 7  
28 (32)) to allow ingress of a second stent as shown in  
29 figure 7.

30

31 It can be appreciated that various improvements and  
32 modifications can be made without departing from the

1 scope of the present invention. In particular it  
2 can be envisaged that the valve may be formed from  
3 at least two leaflets, which in a resting position  
4 are urged towards each other minimising blood flow  
5 from the second cardiovascular compartment into the  
6 first cardiovascular compartment. On movement of  
7 blood in a first direction through the stent, from  
8 the first compartment to the second compartment,  
9 these leaflets may be pushed apart from each other,  
10 enabling blood flow from the first compartment into  
11 the second compartment. During diastole the two  
12 leaflets of the valve will be urged towards each  
13 other due to the resilience of the material.  
14 Alternatively, different methods may be used to  
15 align the stents along their longitudinal length  
16 such as providing junction means.

17

18

19